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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,115	04/29/2005	Yoshiko Takayama	2005_0740A	2341

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EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
04/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,115	TAKAYAMA ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/22/09 has been entered.

Status of Application/Amendments/claims

2. Applicant's amendment filed 1/22/09 is acknowledged. Claims 1-12 are cancelled. Claims 13-16 are amended. Claims 13-22 are pending in this application and are under examination in this office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

4. Applicant's arguments filed on 1/22/09 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections Withdrawn

5. The rejection of claims 13-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in response to Applicant's amendment to the claims and Applicant's arguments.

Claim Rejections/Objections Maintained

In view of the amendment filed on 1/22/09, the following rejections are maintained.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-16 and 18-21 stand rejected under 35 U.S.C. 102 (b) as being anticipated by Nordisk (WO98/58646, published on Dec 30, 1998 as in IDS). The rejection is maintained for the reasons made of record.

Claims 13-16 and 18-21 as amended are drawn to methods of promoting extension of corneal nerve axon, recovering decreased corneal sensitivity and treating eye disease in a subject with a damaged or cut corneal nerve axon and a method of treating corneal epithelium in a subject with defective corneal epithelium with an SSTR2 or SSTR4 agonist.

On p. 5-6 of the response, Applicant argues that Nordisk does not anticipate the instant claims or render the instant claims obvious because independent claims 13-15 have been amended to recite “a subject with a damaged or cut corneal nerve axon” and independent claim 16 has been amended to recite “a subject with defective corneal epithelium”. Applicant argues that Nordisk does not teach the recited patient population in instant claims because Nordisk only teaches patients with high interocular pressure

and/or deep ocular infections. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, Nordisk does anticipate the claimed method because Nordisk does teach treating patients with a damaged corneal nerve axon as recited in instant claims 13-15 and does teach patients with defective corneal epithelium as recited in instant claim 16.

Although Nordisk does not explicitly teach that patients with glaucoma or other eye inflammatory disorders have a damaged or cut corneal nerve axon, it is known in the art that glaucoma causes corneal/optic nerve damage as evidenced by the data of NEI (retrieved on April 9, 2009 from the website of http://www.nei.nih.gov/glaucoma/printpage.asp?ref=http://www.nei.nih.gov/glaucoma/content/english/faq.asp). In addition, inflammation of corneal stroma, stromal keratitis and conjunctivitis causes corneal nerve damage as evidenced by Oduntan (see p. 287, abstract, J. Anat 2005, 206: 287-294). Thus, Nordisk does teach patients with a damaged or cut corneal nerve axon and anticipates the methods as recited in instant claims 13-15 and 18-20 because Nordik teach a method of treating glaucoma, inflammation of corneal stroma, stromal keratitis and conjunctivitis with somatostain (see abstract; p.3, p.5; p9-23 for somatostatin receptor agonists).

In addition, as previously made of record, Nordisk teaches a method of treating several eye diseases including glaucoma, inflammation of corneal stroma, stromal keratitis, iritis, retinitis, cataract and conjunctivitis by somatostatin (see abstract; p.3, p.5; p9-23 for somatostatin receptor agonists). The diseases of conjunctivitis,

inflammation of corneal stroma, and stromal keratitis also cause defective corneal epithelium defect as evidenced by Suzuki et al. (see p. 550, abstract, Suzuki et al. Curr Eye Res. 2000. 21:550-553) and Fini et al. (see p. S12 2nd col., Fini et al. Arch Dermatol. Res. 1998. 290: S12-S23).

Conjunctivitis, inflammation of corneal stroma and stromal keratitis (herpes virus infection on cornea) causes defective corneal epithelium because these diseases affect cornea and the cornea encompasses five layers of cells including epithelium, Bowman's membrane, stroma, Descemet's membrane and endothelium (from outside to inside of the cornea; as previously on p.3-4 of the data retrieved from the NEI website, www.nei.nih.gov/health/cornealdisease, cited in a prior office action). Suzuki et al. teach that conjunctival inflammation (conjunctivitis) induces migration of Langerhans cells in donor or recipient corneal epithelium to cornea and consequently affect survival of corneal allografts (see p. 550, abstract). Fini et al. teach that corneal ulceration can be caused by stromal keratitis (herpes virus infection on cornea) and stromal ulceration is initiated by defective healing of corneal epithelium (see p.S13, 2nd col & table 1). Thus, patients with conjunctivitis and inflammation of corneal stroma and stromal keratitis are patients with defective corneal epithelium. Thus, Nordisk teaches patients with defective corneal epithelium and anticipates the method recited in instant claims 16 and 21 because Nordisk teaches a method of treating patients with conjunctivitis, inflammation of corneal stroma, stromal keratitis with somatostatin and these patients are subjects with corneal epithelium defect as recited in instant claim 16.

Note that

"The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). " See MPEP § 2112.01 [R-3].

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nordisk (WO98/58646, published on Dec 30, 1998 as in IDS) in view of Perez-Santonja et al. (Am J. Ophthalmol. 1999. 127:497-504).

Claims 13-22 as amended are drawn to methods of promoting extension of corneal nerve axon, recovering decreased corneal sensitivity and treating eye disease in a subject with a damaged or cut corneal nerve axon and a method of treating corneal epithelium in a subject with defective corneal epithelium with an SSTR2 or SSTR4 agonist, wherein the decreased corneal sensitivity occurs after surgery.

Nordisk is as set forth above in section of the 102(b) rejection. Nordisk does not teach that the decreased corneal sensitivity occurs after surgery as recited in instant claim 17.

Perez-Santoja et al. teach that laser in situ keratomileusis to correct myopia or photorefractive keratectomy can decrease corneal sensitivity (see p. 497, abstract & col.2).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to use somatostatin to treat or recover decreased corneal sensitivity in a subject with a damaged or cut corneal nerve axon wherein the decreased corneal sensitivity results from surgery. The person of ordinary skill in the art would have been motivated to do so with an expectation of success because an eye surgery can cause decreased corneal sensitivity and somatostatin has successfully been used

to treat or recover decreased corneal sensitivity in patients with a damaged corneal nerve axon, such as patients with glaucoma, conjunctivitis, inflammation of corneal stroma, stromal keratitis, which are disorders with a damaged corneal nerve and defective corneal epithelium as taught by Nordisk. Thus, the results of treating or recovering decreased corneal sensitivity after surgery using somatostatin would have been expected.

Conclusion

8. NO CLAIM IS ALLOWED.

9. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
April 2, 2009

/Christine J Saoud/
Primary Examiner, Art Unit 1647